|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **QUESTIONS** | | | **ANSWERS** | | |
| 1. Please provide contact information: | | | Name: | | |
| Business Name: | | |
| Address: | | |
| Phone: | | |
| Email: | | |
| 1. What tests would you like performed at the study timepoints (Potency, pH, sterility, etc.)? See Below | | | | | |
| Option A: | Option B: Select Tests and List Timepoints | | | | |
| **Default to ARL suggested tests** | Test | Timepoints | | Test | Timepoints |
| Potency |  | | Container Closure |  |
| Appearance |  | | Antimicrobial Effectiveness |  |
| pH |  | | Microbial Enumeration |  |
| Particulate Matter |  | | Preservative Quantitation |  |
| Sterility |  | | Endotoxin |  |
| 1. Product Description (Drug name(s), concentration(s)): | | |  | | |
| 1. What is the target beyond use date (BUD)? | | |  | | |
| 1. What is the formulation identification number? | | |  | | |
| 1. Please provide any relevant NDC #’s: | | |  | | |
| 1. cGMP or non-cGMP? | | |  | | |
| 1. Product Type (solution, suspension, emulsion, etc?): | | |  | | |
| 1. Please list any antimicrobial preservatives present: | | |  | | |
| 1. Is this a single or multi-dose container? | | |  | | |
| 1. What is the route of administration? | | |  | | |
| 1. Container type, size, and fill volume? | | |  | | |
| 1. What is the theoretical maximum batch/lot size? | | |  | | |
| 1. What is the average number of lots produced per month? | | |  | | |
| 1. Endotoxin limit, or provide the average patient weight and max dose/hour: | | |  | | |
| 1. Storage Conditions (Room temp, refrigerated, etc.)? | | |  | | |
| 1. If necessary, list any secondary packaging or overwrap needed for sample storage (brown bags, etc.): | | |  | | |
| 1. Should Day 0 be the date compounded or the date received by ARL? | | |  | | |
| 1. Goals of study, comments, or special requests: | | |  | | |

**\*\*Please include a copy of your formulation sheet including any sub-formulas with your completed questionnaire\*\***